

# **Exhibit 5**

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A REGISTERED LIMITED LIABILITY LAW PARTNERSHIP  
INCLUDING PROFESSIONAL CORPORATIONS

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September 17, 2004

**VIA E-MAIL**

To: Counsel of Record for Plaintiffs\*

Re: In re Columbia University Patent Litigation, MDL No. 1592

Dear Counsel:

I am writing in response to the letter from Kirke M. Hasson dated September 15, 2004, which requests on behalf of plaintiffs that Columbia provide certain clarifications of the Covenant Not to Sue filed on September 1, 2004 ("Covenant"). I will respond to the requests in the same order and with the same numerical references as in Mr. Hasson's letter.

1(a). "Covered products" as defined in the Covenant extends not only to vials or lots of such product that were manufactured by a plaintiff on or before September 1, 2004, but also to vials or lots of the same product manufactured by such plaintiff at any time in the future, and to the use and sale of such product.

1(b). "Covered products" as defined in the Covenant extends to all proteins on sale by a plaintiff on or before September 1, 2004, not merely the brand name products that are marketed.

1(c). "Covered products" as defined in the Covenant extends to all proteins on sale by a plaintiff on or before September 1, 2004, even if changes are later made in the process by which such protein is manufactured.

1(d). "Covered products" as defined in the Covenant extends to all proteins on sale by a plaintiff on or before September 1, 2004, even if such plaintiff uses a new DNA construct or a new transformed cell created after September 1, 2004, to express any such protein.

2(a). "Covered products" as defined in the Covenant extends to all transformed cells made on or before September 1, 2004, whether or not amplification of DNA I or DNA II has occurred.

2(b). "Covered products" as defined in the Covenant extends to all DNA constructs made on or before September 1, 2004.

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2(c). “Covered products” as defined in the Covenant extends to all proteins expressed on or before September 1, 2004, made using the transformed cells or DNA constructs referenced in 2(a) and 2(b) or a method covered by the ’275 patent as it currently reads.

2(d). The Covenant extends to the continued production, use or sale after September 1, 2004, of the transformed cells, DNA constructs, and proteins referenced in 2(a), 2(b), and 2(c).

3(a). The Covenant extends to the future manufacture, use, or sale by a plaintiff of anything that such plaintiff had produced on or before September 1, 2004, such as a transformed cell, a DNA construct, or a cell line that had been made on or before September 1, 2004, regardless of whether that thing had yet led to any commercially sold product.

3(b). The Covenant extends to the future manufacture, use, or sale by a plaintiff of a protein that such plaintiff had made on or before September 1, 2004, or of a DNA construct, transformed cell, or cell line expressing that protein, where the protein was in pre-clinical or clinical trials on or before that date.

4(a). If a scientist working at a plaintiff creates for the first time after September 1, 2004, a DNA construct or a cotransformed cell, such as a first cotransformation with a DNA I encoding for a particular protein, the Covenant does not extend to such DNA construct or cotransformed cell, unless such protein encoded by the DNA construct or cotransformed cell was on sale by such plaintiff on or before September 1, 2004.

4(b). If a scientist at one of the plaintiffs creates for the first time after September 1, 2004, a DNA construct or a cotransformed cell, such as a first cotransformation with a DNA I encoding for a particular protein, the Covenant does not extend to methods of using such DNA construct or cotransformed cell, unless such protein encoded by the DNA construct or cotransformed cell was on sale by such plaintiff on or before September 1, 2004.

4(c). If a scientist at one of the plaintiffs creates for the first time after September 1, 2004, a DNA construct or a cotransformed cell, such as a first cotransformation with a DNA I encoding for a particular protein, the Covenant does not extend to a protein produced using such DNA construct or cotransformed cell, unless such protein encoded by the DNA construct or cotransformed cell was on sale by such plaintiff on or before September 1, 2004.

5(a). The letter dated September 10, 2004 (“September 10 Letter”) was not a modification of the Covenant in stating that: “The Covenant applies to any claim of any

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reissued or reexamined version of the '275 patent that is the same as, or substantially identical to, a claim of the '275 patent as it currently reads." The quoted statement is simply the legal consequence of the Covenant, as explained in *Spectronics Corp. v. H.B. Fuller Co., Inc.*, 940 F.2d 631 (Fed Cir. 1991), and *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852 (Fed. Cir. 1999).

5(b). The Covenant does not extend to any claim in any patent that may issue in the future based on the '159 application, without exception.

5(c). Other than the '159 application and the '275 patent reissue application, there are no pending patent applications that claim priority to U.S. Application Serial No. 06/124,513.

6. Columbia cannot confirm any of these statements with respect to possible relationships that plaintiffs may elect to have in the future with unidentified third parties regarding "covered products." The statements are simply too theoretical. Your letter does not identify any such current relationship between a plaintiff and a third party regarding a "covered product." If any plaintiff has a current contractual (or other) relationship with a third party regarding a "covered product" that such plaintiff believes creates an actual case or controversy with Columbia concerning the validity, enforceability, or infringement of the '275 patent as it currently reads, please identify such third party and the nature of the relationship and Columbia will consider whether it is necessary to take some action to eliminate an actual case or controversy.

7. The phrase "any claim of patent infringement" as used in the Covenant includes direct infringement, contributory infringement, and inducing infringement.

If you believe that there are any other issues concerning the Covenant that require clarification, please contact me so that we may attempt to resolve them promptly. I would appreciate your informing me whether plaintiffs are now prepared to stipulate to the relief sought in Columbia's Motion to Dismiss. I request that counsel for any plaintiff who is not prepared to stipulate to the relief sought in Columbia's Motion to Dismiss advise us promptly as to the basis for that opinion so that we may make every effort to eliminate or narrow the issues in dispute.

Very truly yours,



David I. Gindler

cc: Wayne Barsky, Esq.

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